January 15, 1999

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical, and it is presented here exactly as submitted.

December 10, 1998

Mr. Michael Goodis
Chemical Review Manager – Methidathion
Special Review and Reregistration Division
Environmental Protection Agency
401 M. St. SW
Washington, D.C. 20460

SUBJECT: METHIDATHION; EPA REG. NO. 100-530. COMMENTS ON THE HED RED PRELIMINARY RISK ASSESSMENT

Dear Mr. Goodis:

This letter constitutes the initial response of Novartis Crop Protection, Inc. and Gowan Company to the HED Reregistration Eligibility Decision preliminary risk assessment dated October 30, 1998. As instructed by the Agency in the accompanying letter dated November 3, 1998, our comments at this time are limited to matters pertaining to errors, confidential business information and planned future data submissions. Additional comments relating to policy, data interpretation or other issues, including errors or omissions uncovered during subsequent review of the preliminary risk assessment will be submitted during the 60-day public comment period.

As you are aware, EPA's October 30, 1998 preliminary assessment was incomplete in several ways. First, the EFED draft RED chapter, which included significant changes in data requirements and study status was not provided to the registrants until November 23, 1998. This document is under initial review for errors and appropriate comments will be submitted within 30 days of its receipt. In addition, a number of the supporting documents which were to accompany the HED October 30, 1998 preliminary assessment (the RfD/Peer Review Report of Methidathion, the FQPA Report, and the Residue Chemistry Chapter Addenda #1 and #2) were not provided to the registrants until December 3, 1998. Initial comments on errors or omissions in these new documents will be submitted as soon as practicable, but no later than within 30 days of receipt.

I. Errors

The following comments pertain to the HED October 30, 1998 preliminary risk assessment, unless reference to specific support documentation is made.

Page 4 (Executive Summary)

The Agency incorrectly cites citrus, artichokes and safflower as the predominant uses for methidathion. The predominant uses, based on our marketing information, are dormant treatment for nuts and stone fruit, followed by citrus.

Also, we wish to point out that the maximum use rate of 10 pounds a.i./A is only found on the two inactive emulsifiable concentrate registrations. EPA accurately notes that these ECs are not marketed or produced. The maximum use rate for the 25% wettable powder formulation, which is the only active end-use product registration is 5 pounds a.i./A.

Pages 9-11 (Registered Uses)

Please note that the Novartis registrations 100-567, 100-501 and 100-719 have been formally transferred to Gowan Company. The new registration numbers are 10163-237, 10163-236 and 10163-238, respectively.

EPA states that the SLN label for use on clover grown for seed must be amended to include restrictions to prevent food or feed use of treated plant parts. The current SLN label for this use already includes the following extensive feeding restrictions:

Precautions: Do not feed or graze treated growth of clover forage or fodder. Do not cut treated growth of clover for hay or forage. Seeds from treated plants may not be used for sprouts. No portion of the treated field, including seed, seed screenings, hay or forage may be used for human or animal consumption.

Producers of clover seed who use this product, or cause the product to be used on fields they operate, are required to inform, in writing, conditioners receiving seed produced on fields treated with this product. A copy of this labeling is required to be provided to the conditioner by the producer. Processed seed must be labeled "Not for human or animal consumption" at the processing plant. The processor must dispose of all seed screenings in such a way that they cannot be distributed or used for food or feed.

Finally, the Agency reiterates that citrus, safflower and artichokes are the predominant uses, based on % crop treated. According to our marketing information, which is based on pounds sold by crop outlet, the predominant uses are nut and stone fruit dormant uses, followed by citrus.

Pages 13-20 (Occupational Exposure)

It appears that both the October 30, 1998 preliminary risk assessment, as well as the supporting Occupational and Residential Exposure Assessment dated July 19, 1996 include several major sources of error which significantly overestimate actual risk. As noted above, the maximum label

rate for the 25% wettable powder product is 5 pounds a.i. per acre, not 10 pounds a.i. per acre. Furthermore, it appears that the Agency has neglected to include the engineering controls provided by water soluble packaging in the mixer/loader/applicator preliminary assessments. Also, the backpack sprayer and low pressure handwand are not used for application.

The Agency may wish to refer to the Novartis submission dated July 8, 1998, which specifically responded to the July 19, 1996 OREB document. We note that EPA has apparently overlooked the detailed information presented in that submission in the preliminary risk assessment and has calculated exposures that are grossly exaggerated.

Finally, Novartis and Gowan Company maintain that the NOEL of 0.2 mg/kg bw/day used by EPA is inappropriate and that the appropriate NOEL is 5 mg/kg bw/day from the acceptable 28-day dermal toxicity study in rabbits. Novartis will soon be making a submission regarding this endpoint.

II. Confidential Business Information

We do not make any confidential business information claims for any of the information presented by the Agency.

III. Future Data

Comments on future data submissions will be made within 30 days of our receipt and initial review of the EFED draft RED chapter and the four new HED support documents cited above.

Please contact me at (336) 632-2391 if you have any questions or comments.

Sincerely,

Robert E.M. Wurz, PhD
Senior Regulatory Manager

cc: Elizabeth Codrea, Gowan Company